Applicant: Peter M.J. Mulier et al.

Serial No.: 10/014,388 Filing Date: October 22, 2001

Docket No.: M190.105.102 (P-8163.01 Cont 1)

Title: HELICAL NEEDLE APPARATUS FOR CREATING A VIRTUAL ELECTRODE USED FOR THE

ABLATION OF TISSUE

REMARKS

This Amendment is responsive to the Office Action mailed November 2, 2004. In that Office Action, the Examiner rejected claims 21-30 under 35 U.S.C. §103(a) as being unpatentable over Eggers et al., U.S. Patent No. 5,683,366 ("Eggers") in view of Alferness, U.S. Patent No. 4,355,642 ("Alferness"), Hon, U.S. Patent No. 4,321,931 ("Hon") and Mulier et al., U.S. Patent No. 5,431,649 ("Mulier").

With this Response, claims 21 and 23 have been amended. Claims 21-30 remain pending in the application and are presented for reconsideration and allowance.

Claim Rejections under 35 U.S.C. §103

As indicated above, claims 21-30 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Eggers in view of Alferness, Hon and Mulier. Applicants respectfully disagree with the Examiner's rejection.

In raising this §103(a) rejection, the following is provided by the Examiner:

"In figure 21, the Eggers, et al., Patent shows a surgical apparatus having first coil and second coil electrodes in parallel designed in a bipolar configuration and equipped for the infusion of conductive fluid to enhance the conductivity between the electrodes. The Eggers, et al., Patent does not disclose the use of electrodes having helical configurations. However, the use of helical electrodes is conventional in the art as evidenced by the teachings of Alferness, Hon, and Mulier, et al.

The Alferness Patent shows in figures 1-4 above, various electrode configurations that include helical coils. Importantly, figure 3 shows two helical electrodes in parallel in a multi-polar configuration. Additionally, the Hon Patent shows in figure 5 below, an embodiment having two helical electrodes (12, 15) in parallel.

Finally, the Mulier, et al., Patent also discloses the use of helical coils and the infusion of conductive substances. In figure 2, the patent shows a helical coil used for RF ablation. The helical coil includes apertures for the infusion of conductive fluid.

Based on the above observations, it would not be unreasonable to suggest that for a person of ordinary skill in the art, modifying the electrodes in the Egger, et al., Patent with helical electrodes as taught by the Alferness, Hon, and Mulier, et al., would have been an obvious design alternative. Furthermore, based on the teachings of the patents cited in this rejection, and specifically, the Mulier, et al.,

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Patent, the subject matter disclosed in the cited claims appears to suggest a duplication of well known ablation elements as shown in figure 2 above. Accordingly, the mere duplication of figure 2, in a bipolar configuration as disclosed by the Eggers, et al., Patent cannot be considered a novel invention."

First, the Applicants do not understand the Examiner's interpretation of Eggers. In particular, in raising the rejection, the Applicants do not see how figure 21 of Eggers shows "a surgical apparatus having first coil and second coil electrodes in parallel designed in a bipolar configuration" as stated by the Examiner. The word "coil" simply does not appear in Eggers. Consequently, it is unclear how the Examiner is interpreting Egger's to reach his rejection. Applicants request that, should the Examiner maintain this rejection in light of the current Amendment and Response, the Examiner clarify his rejection in any future action, by specifically identifying the reference numerals associated with the electrodes which provide the Examiner with his interpretation of Eggers as set forth above.

Regardless of the Examiner's interpretation of Eggers having "first coil and second coil electrodes in parallel designed in a bipolar configuration", the Examiner's attention is directed to examined claim 21 which actually recites "the first helical coil and the second helical coil wound parallel to one another". Even if Egger's could somehow be construed to teach "first coil and second coil electrodes in parallel designed in a bipolar configuration" as the Examiner states, Eggers does not teach or suggest the first helical coil and the second helical coil wound parallel to one another. (Emphasis added).

Furthermore, none of the Examiner's secondary references provide the missing teachings to overcome the deficiency of Eggers identified above. Turning to Alferness, figure 3 clearly does not teach or suggest the first helical coil and the second helical coil wound parallel to one another. Turning to Hon, figure 5 does not teach or suggest the first helical coil and the second helical coil wound parallel to one another.

Lastly, in considering Mulier, the Examiner states that Mulier "appears to suggest a duplication of well-known ablation elements as shown in figure 2". As shown by the Examiner's cited art, in electrosurgery, bipolar electrodes are often not mere duplications of one another. As part of the summary of the invention for Egger's recites "[i]n irrigant flooded environments, such

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as arthroscopic surgery, the area of the return electrode is sufficiently large to result in low current densities that effectively preclude damage to nearby tissue." (Col. 5, 1. 25-29) Thus, Eggers teaches away from using a return electrode having the same configuration as the active electrode to preclude damage to tissue near the return electrode.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See MPEP 2143.01. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16USPQ2d 1430 (Fed. Cir. 1990). Here, Eggers teaches away from using a return electrode having the same configuration as the active electrode. Consequently, a mere duplication of Mulier may not be properly combined with Eggers.

Furthermore, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Mulier's Figure 6 "illustrates the associated apparatus for administration of conductive solution before and during application of R-F energy to the helical electrode." Col. 2, lines 43-45. In the discussion of Figure 6, Mulier goes on to recite that "[a]n electrosurgical generator 200 for providing R-F electrical energy is illustrated in functional block form, coupled to electrical connector 24 and to a ground plate electrode 202..." Col. 5, 1. 68-Col. 6, 1. 3. Thus, given the presence of a ground plate electrode 202, it is clear that the helical electrode in Mulier is configured and used as a monopolar electrode.

With respect to Mulier, the Examiner states that the present invention is a more duplication of figure 2 of Mulier in a bipolar configuration as disclosed by Eggers. As indicated in the response to the Examiner's previous office action, and reiterated here, this changes the principle of operation of Mulier from a monopolar to a bipolar device and, based on the rule of

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In re Ratti, the teachings of the references are not sufficient to render the claims prima facle obvious.

Notwithstanding the foregoing deficiencies of the rejection against the claims, Applicants have elected to amend independent claim 21 to expedite prosecution, thus rendering any further discussion of the rejection against claims 21-30 moot. Specifically, Applicants have amended independent claim 21 to recite that the first helical coil and the second helical coil are wound parallel together along a common axis. Support may be found in Figure 8, as well as the specification. Apart from independent claim 21, dependent claim 23 has been amended to cure a defect in antecedent basis.

In view of the foregoing amendments and remarks, it is respectfully submitted that amended independent claim 21 is patentable over the Examiner's rejection(s), and the rejection(s) of claim 21 under 35 U.S.C. 103§(a) should be withdrawn upon reconsideration.

Claims 22-30 depend directly or ultimately from amended independent claim 21, and under 35 U.S.C. §112 must be construed to include all of the limitations of independent claim 21 including their own limitations. Accordingly, it is respectfully submitted that claims 22-30 are also patentable over the cited references, and the rejection of claims 22-30 under 35 U.S.C. 103§(a) should be withdrawn upon reconsideration.

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CONCLUSION

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this response.

Respectfully submitted,

Peter M.J. Mulier et al.,

By their attorneys,

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Timothy A. Czaja

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CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper or papers, as described herein, are being transmitted via teleforsimile to Examiner Anh Tuan Tuong Nguyen of Group Art Unit 3763, at Fax No. 703 872-9306 on this _____ day of January, 2005.

Ву__

Name: Timothy